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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,195	12/23/2005	Steven Walter Clavey	50438/002001	4118
21559	7590	07/24/2007	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			CLARK, AMY LYNN	
			ART UNIT	PAPER NUMBER
			1655	
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			07/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

<b>Application No.</b> 10/562,195	<b>Applicant(s)</b> CLAVEY, STEVEN WALTER	
<b>Examiner</b> Amy L. Clark	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER; FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 23 December 2005.
- 2a)  This action is **FINAL**.
- 2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1-25 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) \_\_\_\_\_ is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) 1-25 are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All   b)  Some \*   c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5)  Notice of Informal Patent Application
- 6)  Other: \_\_\_\_\_

Art Unit: 1655

## DETAILED ACTION

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-15, drawn to a composition for treating or alleviating a symptom resulting from gynecological disorder comprising the herbs Chi Shao (*Paeonia obovata*, Root), Dang Gui (*Angelica Polymorpha*, Root), Chuan Xiong (*Ligusticum Wallichii*, Root), Xiang Fu (*Cyperus Rotundus*, Rhizome), Yan Hu Suo (*Corydalis turtshaninovii*, Rhizome) and Tao Ren (*Prunus persica*, Seed), or parts thereof

Group II, claim(s) 16 and 18-25, drawn to a method for prophylactic or therapeutic treatment of a gynecological disorder, comprising the step of administering to a subject requiring such a treatment, a composition according to claim 1.

Group III, claim(s) 17, drawn to a method of alleviating or preventing a symptom resulting from a gynecological disorder, comprising the step of administering to a subject requiring such a treatment, a composition according to claim 1.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Claim 22, at least, is anticipated by or obvious over Tao (A, US PreGrant Publication Number 2002/0039587 A1), in view of Maruo (N, JP 62-111930 A, Translation of abstract provided herein). Tao teaches a composition for treating hand or wrist discomfort, such as pain, soreness, stiffness, and general discomfort including symptoms due to abnormalities in muscles, ligaments, nerves, bones, and joints in the hand or wrist area (See Abstract and paragraph 0072) comprising *Paeonia obovata* (See paragraph 0075), *Ligusticum wallichii* root (See paragraph 0076), *Corydalis turtshaninovii* Bess. (See paragraph 0080) and *Angelica polymorpha* (See paragraph 0081). Maruo teaches a medical fluid preparation for rubbing into painful joints comprising *Cyperus rotundus* and *Prunus persica*.

Art Unit: 1655

It is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

Consequently, the special technical feature which links the claims does not provide a contribution over the prior art, so unity of the invention is lacking.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with

Art Unit: 1655

an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Please note, in order to be response, Applicant is required to elect Specie A or Specie B or Specie C or Specie D or Specie E or Specie F or Specie G. Applicant is further required, once Applicant has elected from between A-G, to elect from within the specie elected from each of the following (not between each of the following but one election from each subspecies): i) one type of extract from claim 10 or 13, **and** also elect from ii.) one form of administration from claim 11, 14 or 15.

Group I:

Specie A: Elect claims 1 and 2.

i.) Further elect either extract from claim 10 or powder from claim 13.

ii.) Further elect **one form** of administration from claim 11, **or one form** of administration from claim 14, **or one form** of administration from claim 15.

Specie B: Elect claims 1, 3 and 4.

i.) Further elect either extract from claim 10 or powder from claim

Art Unit: 1655

13.

ii.) Further elect **one form** of administration from claim 11, **or one form** of administration from claim 14, **or one form** of administration from claim 15.

Specie C: Elect claims 1, 3 and 5.

i.) Further elect either extract from claim 10 or powder from claim

13.

ii.) Further elect **one form** of administration from claim 11, **or one form** of administration from claim 14, **or one form** of administration from claim 15.

Specie D: Elect claims 1, 3 and 6.

i.) Further elect either extract from claim 10 or powder from claim

13.

ii.) Further elect **one form** of administration from claim 11, **or one form** of administration from claim 14, **or one form** of administration from claim 15.

Specie E: Elect claims 1, 3 and 7.

i.) Further elect either extract from claim 10 or powder from claim

13.

ii.) Further elect **one form** of administration from claim 11, **or one form** of administration from claim 14, **or one form** of administration from claim 15.

Specie F: Elect claims 1, 3 and 8.

i.) Further elect either extract from claim 10 or powder from claim

13.

ii.) Further elect **one form** of administration from claim 11, **or one form** of administration from claim 14, **or one form** of administration from claim 15.

Specie G: Elect claims 1, 3 and 9.

i.) Further elect either extract from claim 10 or powder from claim

13.

ii.) Further elect **one form** of administration from claim 11, **or one form** of administration from claim 14, **or one form** of administration from claim 15.

Please note that only the claims elected from within the specie elected and subspecies elected will be examined. All other claims will be withdrawn from consideration.

Group II: Please note that Applicant is required to elect from within i.) **and** within ii.), not between i.) and ii.) to be responsive.

i.) Elect one or more disorder from claim 18.

Art Unit: 1655

When making this election, Applicant should note that the disorder elected must correspond with the composition and that in electing all of the diseases, Applicant is asking the Examiner to elect all of the diseases as one disease to be treated by the composition, not individual diseases. For example, if Applicant elects all three diseases, then Applicant is electing all diseases as one disease rather than three distinct diseases.

ii.) Further elect one form in which the composition is administered from claim 22 or claim 24.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Group I:

- Specie A: Claims 1 and 2, and either 10 or 13, and either 11, 14 or 15.
- Specie B: Claims 1, 3 and 4, and either 10 or 13, and either 11, 14 or 15.
- Specie C: Claims 1, 3 and 5, and either 10 or 13, and either 11, 14 or 15.
- Specie D: Claims 1, 3 and 6, and either 10 or 13, and either 11, 14 or 15.
- Specie E: Claims 1, 3 and 7, and either 10 or 13, and either 11, 14 or 15.
- Specie F: Claims 1, 3 and 8, and either 10 or 13, and either 11, 14 or 15.
- Specie G: Claims 1, 3 and 9, and either 10 or 13, and either 11, 14 or 15.

Group II:

- i.) Claims 16, 25, 18 and claim 19, claim 20 or claim 21.
- ii.) Claims 16, 25 and claim 22 or 24. If oral administration is elected, then

Art Unit: 1655

additionally claim 22.

The following claims are generic: Claims 1, 3, 15, 16, 18 and 22.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

There is no common structural element shared by all the alternatives.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 1655

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
MICHELE FLOOD  
PRIMARY EXAMINER

Amy L. Clark  
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Amy L. Clark  
July 6, 2007